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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,112	11/20/2003	Johannes Bartholomaus	107101-10	8885

27384 7590 11/18/2009

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
11/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,112	BARTHOLOMAUS ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7,8,27-29,31,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7,8,27-29,31,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims and Previous Rejections/Objections Status

1. Claims 1,2,4,7,8,27-29,31,41 and 42 are pending in the application.

2. The objection to claim 1 is withdrawn.

3. The rejection of claims 11,2,4,6-8,29 and 31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over application 10/567,594 is withdrawn.

4. The rejection of claims 1,2,4,7,8,27-29,31,41 and 42 under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 2003/0064099A1) is withdrawn.

Terminal Disclaimer

5. The terminal disclaimer filed on 7/30/09 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/567,594 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Declaration/Affidavit

6. The declaration under 37 CFR 1.132 filed 7/30/09 is insufficient to overcome the rejection of claims 1,2,4,7,8,27-29,31,41 and 42 under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 2003/0064099A1) based upon the rejection as set forth in the last Office action because: the declaration of Heinrich Kugelmann states that the polyethylene oxide (PEO) must be employed in a sufficient quantity to yield

tablets having a breaking strength of at least 500N. If the quantity of the polyethylene oxide is too low the desired breaking strength cannot be achieved (p2, last paragraph; p2, table).

7. The reference of Oshlack et al. teaches of the use of PEO polymer in the tablets of the disclosure in a ratio to the opioid agonist of from about 1:15 to about 15:1 weight (Oshlack et al. p4, [0050]) which encompasses the limitation of component (C) being present in an amount of at least 30 wt.-% as stated in the amended claim 42. Therefore the tablets of the disclosure encompass the tablets of the instant claims and are capable of the same functions and the same properties, such as breaking strength. The declaration does not appear to be a showing of unexpected results. The declaration only shows a property of using PEO; however, the cited art teaches the use of the same amount of PEO, thus it must have the same property.

Claim Objections

8. Claim 41 is objected to because of the following informalities: the claim identifier is incorrect and should read (currently amended). Appropriate correction is required.

Response to Arguments

9. Applicant's arguments with respect to claims 1,2,4,7,8,27-29,31,41 and 42 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1,2,4,7,8,27-29,31,41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 2003/0064099A1) in view of DOW Technical Data, POLYOX^{TM} WSR, February 2003.

12. Oshlack et al. (US 2003/0064099A1) discloses a sustained release dosage form which comprises a.) oxycodone, b.) an aversive agent/gelling agent, such as polyethylene oxide, c.) waxes, etc. (p2, [0026]; p8, [0097]; p9, [0106-0111]; p4-5 [0049] and [0056]). The PEO polymer may be present in the tablets in a ratio to the opioid agonist of from about 1:15 to about 15:1 by weight (p4, [0050]) which encompasses the limitation of component (C) being present in an amount sufficient to result in a breaking strength of at least 500N, such as of at least 30 wt.-% of the instant claims. The dosage form may be prepared via melt-extrusion techniques which involves blending the opioid with PEO to form a matrix, heating the matrix to a temperature sufficient to soften the mixture, extruding through a twin-screw extruder and optionally compressing (p8, [0096]; p9, [0109] and [0111]; p10, [0113] and [0120]). The melt-extrusion technique of Oshlack et al. encompasses the sintering technique of the instant claims where the dosage form components are mixed and the resultant mixture is press-formed with preceding exposure to heat. Suitable controlled release tablets may be formulated from

multiparticulate formulations, wet granulation that is compressed into a tablet or melt and may contain hydrophobic binders, such as carnauba wax (p8, [0099]; p9, [0110-0111]; p10, [0120]). Oshlack et al. does disclose a PEO of molecular weight 1-15 million and does not explicitly disclose the dosage form having a breaking strength of at least 500N.

13. DOW Technical Data, POLYOX™ WSR, February 2003 discloses the use of high molecular weight POLYOX™ WSR (i.e. 7,000,000 amu) for sustained release solid dosage forms and are excellent choices for melt processing (p1, paragraph 1). The melt flow of the high molecular weight grades may be improved via the addition of plasticizers (p1, column 2, paragraph 1). POLYOX™ WSR and a plasticizer were used in a solid dosage form to demonstrate the low temperature (65 to 70°C) extrusion of POLYOX™ WSR which uses a single screw extruder (p2, column 1, paragraph 1). POLYOX™ WSR is well suited to thermoplastic processing and can be processed in various solid dosage forms which exhibit sustained release properties based on polymer molecular weight, extrusion temperatures range from 80 to 190°C (p3, conclusions).

14. At the time of the invention it would have been obvious to one skilled in the art to use the POLYOX™ WSR of high molecular weight of the DOW technical data of POLYOX™ WSR for the sustained release dosage forms of Oshlack et al. as both disclosures are drawn to sustained release dosage forms having PEO polymers which are used for the preparation of thermoformed tablets. Further, the opioid and PEO polymer dosage forms of Oshlack et al. contain the PEO polymer in a ratio to the opioid agonist of from about 1:15 to about 15:1 by weight and are prepared via a melt-

extrusion technique, which encompasses the sintering preparation process of the instant claims.

15. Therefore, at the time of the invention it would have been obvious to one ordinarily skilled in the art that the sustained release dosage forms of the combined references of Oshlack et al. and DOW technical data of POLYOX™ WSR contains a high molecular weight PEO polymer in an amount sufficient to result in a breaking strength of at least 500N. If the prior art teaches the composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product as the instant claims do not provide the necessary limitations to distinguish the abuse proof dosage form over the prior art.

16. It is respectfully pointed out that instant claim 29 is a product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618